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SUBMITTING EVIDENCE TO A SCOTTISH PARLIAMENT COMMITTEE

DATA PROTECTION FORM

Name:	Mason Institute for Medicine, Life Sciences and the Law, University of Edinburgh, School of Law
Date:	4 September 2018
Organisation: (if required)	Mason Institute for Medicine, Life Sciences and the Law
Topic of submission:	Human Tissue (Authorisation) (Scotland Bill) - call for views

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HEALTH AND SPORT COMMITTEE**HUMAN TISSUE (AUTHORISATION) (SCOTLAND) BILL****SUBMISSION FROM: The Mason Institute for Medicine, Life Sciences and the Law, University of Edinburgh, School of Law**

The Mason Institute ('MI') is an interdisciplinary network aimed at investigating the ethical, legal, social and political issues at the interface between medicine, life sciences and the law. The MI provides internationally-recognised academic and policy leadership in the socio-legal, medical and life science governance, and bioethics fields.

This response is provided in response to the Committee's call for views on the Human Tissue (Authorisation) (Scotland) Bill ('the Bill'). We note that the Committee is seeking views on the following questions, which we address in turn below:

- What do you think are the key strengths and weaknesses of the proposals to introduce 'deemed authorisation' for those who have not made their wishes on organ donation known?
- What do you think are the key strengths and weaknesses of the plans for authorisation of pre-death procedures?
- Do you have any other comments to make on the Bill?

In summary, the MI recognises and supports the policy objectives of the Bill, but would emphasise that legislation is but one step towards improving transplantation rates, and that a holistic package of measures (both regulatory, social and ethical) are necessary to secure these policy objectives.

Consultation questions

What do you think are the key strengths and weaknesses of the proposals to introduce 'deemed authorisation' for those who have not made their wishes on organ donation known?

The MI recognises and supports the policy objectives of the Bill's proposals on 'deemed authorisation', in terms of seeking to ensure that those who wish to donate organs are able to do so, with the aim of increasing the number of organs available for transplant in Scotland. There are a number of routes through which these policy objectives might be secured – including mandated choice¹ – which have been considered, but discounted in

¹ Policy memorandum, para 138

favour of a soft opt-out system. We note that these alternatives do not come within the ambit of this consultation at present, but would expect their feasibility to be kept under review should an evidence base emerge that points towards an alternative approach.

The Policy Memorandum that accompanies the Bill sets out the drivers for this move to a soft opt-out system, and the background to the Bill, which we will not repeat in this response. However, from our work in this and related fields, we would highlight the following points for consideration by the Committee:

The limits of the law

As has been recognised at Paragraph 30 of the Policy Memorandum, there is limited evidence that demonstrates that legislative change alone will increase the available number of viable organs. Evidence from Wales, following their legislated move to a soft opt-out system for consent to deceased organ and tissue donation, has not, so far, been conclusive, with an insignificant change in the absolute number of ‘donations’.²

Looking further afield to Spain, which is reported to have the world’s highest rate of organ donation,³ it has been suggested, perhaps controversially, that the opt-out donation model per se is a ‘distraction in the quest for increasing rates of organ donation’.⁴ In addition to points made regarding the profile and availability of potential donors in Spain, as compared to the UK, this analysis highlights the role of the ‘transplant coordinator’ role in the Spanish system, as well as the crucial role of the family. We too would emphasise, as has been recognised by the Committee, that legislation is but one step towards improving transplantation rates, and that a holistic package of measures (both regulatory, social and ethical) are necessary to secure the policy objectives of the Bill. Even within the proposed legislation there are still likely to be situations where there is a conflict between the wishes of a family member(s) and the deceased (whether this is a registered decision or comes within the ambit of a deemed authorisation). Here it might be evidentially difficult to distinguish between cases where there is a family objection as opposed to where the deceased has genuinely indicated their wish not to donate (or did wish to donate but had since changed their mind). A holistic package of measures to support the Bill is therefore likely to include:

² <https://gov.wales/docs/dhss/publications/171204organ-donation-annual-report-en.pdf>

³ Fabre, J et al, Presumed consent: a distraction in the quest for increasing rates of organ donation, BMJ 2010;341:c4973, <https://www.bmj.com/content/341/bmj.c4973>

⁴ Ibid.

- (i) adequate staff provision and training, including dealing with family objection;
- (ii) information campaigns regarding organ donation and the opt-out system, and even the possibility of establishing a formal system of transplant coordinators in the NHS;
- (iii) The role of transplant coordinators under such a scheme could be to enter open dialogue with the family of a patient's death after they have been informed of the death of a loved one and when concerns or objections have been raised. Here, the development of appropriate communication skills will be crucial. These should extend to all health care professionals charged with informing families about the death and raising the spectre of the organ donation model.

While it is accepted that family members would have no legal veto as such, ethics and standards of professional conduct require full and proper engagement with relatives and their concerns.

Capturing multiple dimensions of impact

The inconclusive evidential position also emphasises the need to ensure rigour in gathering evidence of the impact of the Bill, and in keeping its provisions under review. While caution is urged as to the limits of law, we consider that there is some force in mandating evidence gathering and evaluation that will contribute to the evidence base in this contested area over time and across the country.

In this regard we note, in particular, that in the proposed Bill there is no provision, equivalent to that found at Section 2 of the Human Transplantation (Wales) Act, which imposes a duty to report to parliament annually. We would suggest that incorporation of such a duty to the Bill would be of benefit, for the reasons set out above, as well as to ensure consistency as between the four countries of the UK.

Whether incorporated into legislation, or as a policy measure alongside this, we would also urge careful consideration of *how* the impact of the Act is captured. For example, we would expect that this would go beyond quantitative measures of the number of deceased donors (although this is clearly important). For example, data collected should include not just information about deaths and 'successful' rates of donation, but also cases where donation was not possible, or objection was raised, and other circumstances in which the model might be operating sub-optimally. It is also important that public responses to educational activities and information campaigns are captured, and that trends regarding general public awareness and support of the opt-out system across Scotland are monitored.

What do you think are the key strengths and weaknesses of the plans for authorisation of pre-death procedures?

The range of issues the plans for authorisation of pre-death procedures could engage are contained within the Policy memorandum, and also duplicate those above, albeit that they may be heightened in relation to the sensitive pre-death period.

We would comment in particular in relation to the moment of death which is not, at present, defined in statute in the UK. Guidance can be gleaned from case law, and also from policy papers, such as those issued by the Academy of Medical Royal Colleges on ‘An ethical framework for donation after confirmation of death using neurological criteria (DBD)’⁵ and ‘An ethical framework for controlled donation after circulatory death’.⁶ While these are designed to assist clinicians to make decisions with confidence in the context of donation after death (and, by extension, pre-death procedures), it is likely that further support will be required alongside the introduction of the Bill. Given our contribution above, there are important issues to consider about the timing of information about the opt-out model/approaching relatives/engaging open dialogue etc – all relative to the timing of death as a matter of clinical assessment.

Do you have any other comments to make on the Bill?

In terms of promoting the Act, we note reference to marketing to specific populations is referred to at Paragraph 45 of the Policy Memorandum. We note that this should always be underpinned by a strong evidential base, and subject to robust evaluation, to ensure effectiveness and reach. More importantly, this should always be carried out with the understanding that targeted outreach can result in stigmatisation and discrimination, and that any such measure needs to take those unintended consequences into account.

⁵ http://www.aomrc.org.uk/wp-content/uploads/2016/07/Ethical_framework_donation_after_confirmation_death_using_neurological_criteria-2.pdf

⁶ http://aomrc.org.uk/wp-content/uploads/2016/04/Ethical_framework_donation_circulatory_death_1211-3.pdf